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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,004

09/08/2004

Hiroshi Sugiyama

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,004

Applicant(s)

SUGIYAMA ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/8/2004, 6/12/2006 & 1/10/2007.

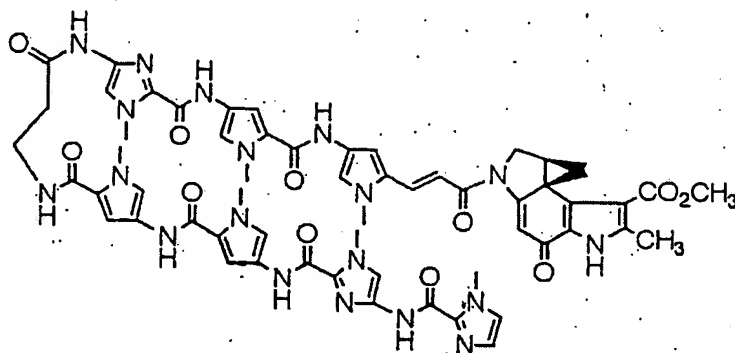
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DETAILED ACTION

Claims 1-12 are pending in the application.

Election/Restrictions

Applicant's election with traverse of species 1 (or Compound 16 found in Figure 5, reproduced below) in the reply filed on May 23, 2007 is acknowledged.



The traversal is on the ground(s) that the claims possess the same or corresponding special technical feature. Applicant's arguments has been considered and found persuasive. The election of species was for examination purposes only. Claims 1-12 have been examined.

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Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on September 8, 2004, June 12, 2006 and January 10, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement

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requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the hairpin polyamides of Formula [12] and Formula [3] when the k , p , q , m and n are defined as a natural numbers from 1 to 10 (see page 5 of the instant specification), does not reasonably provide enablement for any hairpin polyamide having an alkylation reaction site via a vinyl linker or a hairpin polyamide of Formula [1] in which the R^1 variable definition is unknown or compounds of Formulas [2] and [3] wherein the k , p , q , m and n variables are defined as a natural numbers not embraced by natural numbers 1-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

Applicant is claiming any hairpin polyamide having an alkylation reaction site via a vinyl linker in claim 1 (also see claims 2 and 3). Applicant is also

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claiming an agent having an anti-cancer activity in claim 12.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that cancer therapy, for example, remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, Vol. 286, October 15, 1999, pages 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, to maximize efficacy and minimize toxicity. Cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al., Science, Vol. 286, October

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15, 1999, pages 531-537). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

Applicant has not shown that every any hairpin polyamide having an alkylation reaction site via a vinyl linker presently known to man or will be discovered in the future can be made by the disclosed process when the overall structure is different than the compounds of Formulas [2] and [3] and with any possible substituent that can be embraced by the R^1 variable in Formula [1] of claim 2. Applicant has not that every compound of Formulas [2] and [3] can be made when the k, p, q, m and n are defined as a natural number not embraced by 1-10.

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Further, Applicant has not provided any competent evidence or disclosed tests that are highly predictive for treating all cancers by using any hairpin polyamide having an alkylation reaction site via a vinyl linker.

The breadth of the claims

The breadth of claim 1 is any hairpin polyamide having an alkylation reaction site via a vinyl linker. The breadth of claim 2 is a compound of Formula [1] but it is unknown what substituents are embraced by the R^1 variable. The breadth of claims 2 and 3 wherein the k, p, q, m and n variables are defined as a natural number.

The breadth of claim 12 is treating any cancer by using any hairpin polyamide having an alkylation reaction site via a vinyl linker.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological

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activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. The specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. In re Gardner, 166 USPQ 138 (CCPA 1970).

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the

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prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The broad terminology in claim 1, any hairpin polyamide having an alkylation reaction site via a vinyl linker, and the fact that the R^1 variable has not been defined, makes the claims indefinite because the metes and bounds of the claims cannot be ascertained.

In claims 2 and 3, the variables k, p, q, m and n are defined as a natural number and should entail a

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range as found on page 5 of the instant specification of 1 to 10.

Claims 4-7 and 9 do not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 and 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Bando et al.

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{Chemistry - A European Journal, October 18, 2002,
8(2), pages 4781-4790}.

Bando et al. disclose, for example, Compound 13 on page 4783, which is embraced by the instant claimed invention. Therefore, Bando et al. anticipate the instant claimed invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

August 2, 2007